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ONTARIO MINISTRY OF ENVIRONMENT LABORATORIES

QUALITY MANAGEMENT PLAN

1991

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ONTARIO MINISTRY OF ENVIRONMENT LABORATORIES

QUALITY MANAGEMENT PLAN

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ABSTRACT:

This document outlines the Quality Management program for the Laboratory Services Branch and Regional laboratories of the Ontario Ministry of the Environment. It defines the policy, goals, and objectives, and describes the strategy for implementing the program. It identifies the responsibilities and tasks of laboratory staff to document and maintain the program, and to ensure that analytical data measured and reported by these facilities is of known and acceptable quality.

MOE LABORATORIES QUALITY MANAGEMENT PLAN - 1991

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MOE LABORATORIES QUALITY MANAGEMENT PLAN - 1991

1. QUALITY MANAGEMENT PLAN

1.1. INTRODUCTION

1.1.1. Scope

This Quality Management Plan (QMP) for the Ontario Ministry of the Environment, Laboratory Services Branch (LSB), and Regional Laboratories establishes formal responsibility on the part of the Section Managers, the Regional Laboratory Chiefs, the Quality Assurance Office, and staff, to develop and implement a comprehensive, verifiable Quality Assurance Program.

1.1.2. Significance

Clear identification and unambiguous assignment of staff responsibilities and tasks is critical. Strong management direction and support is considered to be an essential ingredient in the formulation and implementation of a successful Quality Management Plan.

Communication and action are the keys to success. All laboratory staff (clerical, technical, scientific, and management) have clearly defined roles, and are individually accountable for the validity and integrity of all data produced for every laboratory client.

1.2. BACKGROUND

1.2.1. Planning for Quality

As partners in program design, management, and implementation, and in data interpretation, laboratory staff will assist clients in the three elements which most affect project and data quality:

a) a succinct statement of project objectives, including specific data quality objectives (DQO);
b) sampling and analysis protocols;
c) sources of data uncertainty and bias and their relative importance to data interpretation.

These three elements have an integrated impact on the overall quality of analytical data produced. They affect project design and the selection of appropriate field and laboratory operations.

1.2.2. Factors Affecting Quality

The interpretation of a client's data is affected by:

a) the variability of the environment being sampled and examined;

b) the uncertainty or bias introduced by field activities;
- sampling design,
- field operations,
- sample preservation,
- sample transportation and storage,

c) the uncertainty or bias introduced by laboratory activities;
- delay before initiating analysis,
- sub-sampling for analytical purposes,
- analytical method selection,
- sample pre-treatment or preparation,
- accuracy of standards,
- calibration and operation of the detection system,
- analytical control protocols,

d) errors in data reporting and data management;

e) inadequate documentation of field and laboratory procedures and related observations.

From a laboratory perspective, the uncertainty or bias due to the analytical process must be minimized if the impact of the other factors is to be measured and ultimately controlled. Therefore, it is essential that systems be established within the laboratory which define the level of quality to be achieved, the protocols to be followed, and the procedures required to document and report that quality to the laboratory client.

1.3. MOE LABORATORIES QUALITY MANAGEMENT

1.3.1. Policy Statements

The Quality Management Plan (QMP) operates within the following policy statements:

a) All analytical services provided by the Laboratory Services Branch and Regional laboratories in support of programs of the Ontario Ministry of the Environment (MOE), shall produce data of known quality which are appropriate to the particular program requirements and the nature of the analytical technology available for the types of samples involved.

b) The quality of all analytical data will be supported by appropriate documentation acceptable to the scientific community at large, and gathered in accordance with established ministry protocols.

c) The quality of the data will be maintained within the framework of an ongoing Quality Management System whereby staff responsibilities and operational procedures are defined, documented, and subjected to audit on a regular basis, with timely corrective action taken as needed.

d) Laboratory Managers, Regional Laboratory Chiefs and Quality Assurance Office staff are responsible for the implementation of this Plan.

1.3.2. Goal Statements

It is the goal of the Ministry of the Environment Laboratories to:

a) ensure that the quality of all analytical data is well controlled, routinely assessed, and documented;

b) ensure that this quality meets program DQO's.

1.3.3. Objectives

To achieve the above goals, the QM Plan has the following objectives:

a) To ensure all necessary protocols and procedures are documented, known to staff, and available for scrutiny;

b) To ensure all analytical systems are operated in accordance with established QA/QC protocols, that these are sufficient to maintain quality, and that timely corrective action is taken to resolve problems;

c) To ensure that regular reports on the quality of laboratory operations are prepared for management action as required;

d) To implement a process of independent audits of laboratory methods, records, and system performance, in order to verify that quality is being maintained;

e) To develop mechanisms for reporting QA/QC and related project-specific data quality information to laboratory clients and to assist them in data interpretation.

1.3.4. Implementation Strategy

The QM Plan is implemented by laboratory management within the LSB and Regional laboratories through Section Technical Committees (STCs).

The activities of the STCs will be developed by the Section QA Coordinators and the staff of the Quality Management Office based on guidance from the Managers QM Committee.

Note: Here, and in the remainder of this document, the word Section refers to organizational activities at either LSB or Regional Laboratories.

The status of the Plan, and the activities of the STCs, will be monitored quarterly by the MOE Laboratories Quality Assurance Committee.

1.4. MOE LABORATORIES QM DOCUMENTATION

The Quality Assurance Officer, in cooperation with the Section QA Coordinator, is required to prepare and maintain the following documents for review, approval and adoption by Laboratory Managers.

1.4.1. QA Policies and Guidelines

This document delineates the generally accepted Good Laboratory Practices (GLPs), and other statements of normal operating conditions within LSB and Regional laboratories, which may impact on data quality, data reporting, or data interpretation. It provides the basis for Section Quality Assurance Programs, and QA Office and Section QA Workplans.

1.4.2. Operational Protocols

These record the routine non-analytical activities required of staff. They are derived from a consideration of the above Policy and Guidelines manual, whereby the more critical facets of laboratory operation will be formalized (e.g. method approval, data reporting, etc).

1.4.3. Laboratory QA/QC Protocols

These record the recommended QA/QC protocols and procedures available for routine use by staff. These may be subject to revision within the Section QA Manual where such is warranted (e.g. control charting approaches, use of control samples and materials, container cleaning protocols).

1.4.4. Analytical Methods Manuals

These record the individual detailed analytical procedures employed in the Laboratories. Method documentation, classification, audit, management approval, updating, and distribution is coordinated by the QA Office staff. Individual method documentation is the responsibility of the Manager and staff of the Sections according to formats and protocols developed by the QA Office and Sectional QA Coordinators.

1.4.5. Quality Management Office Business Plan

This document outlines the scheduled tasks of QA Office staff in support of the Branch and Section QM programs. It will be updated regularly (at least annually).

1.5. SECTION QA DOCUMENTATION

1.5.1. Introduction

It is the responsibility of each Manager and Regional Laboratory Chief to implement and maintain a comprehensive and fully documented Section Quality Assurance Program. The following documents are components of a comprehensive Quality Assurance program.

1.5.2. Section QM Strategy

This document defines how operations and data quality will be managed within each Section. It assigns to staff specific responsibilities with respect to the management, documentation, and reporting of QA/QC information and activities. It also establishes the Section Technical Committee and/or Section QA Coordinator to oversee all QA/QC related activity within the Section in cooperation with the QA Office.

1.5.3. Section Operational and QA/QC Protocols

This document identifies and records, for each workstation and test procedure:

- those operations, equipment, reagents or other supplies, which are critical to operational and data quality;
- protocols followed to ensure their quality, including expected values, control limits, and remedial actions;
- protocols and procedures used to establish, maintain and record routine operational quality, including the process for obtaining approval to restart an analytical system when a problem has been identified.

1.5.4. Section Analytical Methods

These record and must encompass all analytical procedures that have been or may be employed within the Section. All methods must be fully documented, reviewed and audited by the QA Office, and subjected to management approval, prior to use. All method descriptions must be current and available to the QA Office on request.

1.5.5. Section Analytical Performance Summaries

The performance characteristics of all analytical procedures must be available for scrutiny at all times, and be summarized regularly. In general, operational quality should include up-to-date control charts as appropriate.

1.5.6. Section QA Workplan

This workplan, as an essential element of the annual Business Plan, identifies the specific tasks to be accomplished, the persons responsible, and anticipated completion dates, to achieve the activities identified in the Laboratories and Section Quality Management Plan/Strategy. It will be updated regularly (at least annually). A copy of the approved Section QA Workplan shall be provided to the QA Office.

2. QUALITY MANAGEMENT RESPONSIBILITIES

2.1. MANAGEMENT

2.1.1. Director

a) Ensure that the Laboratories Quality Management Plan is implemented by Section Managers, Regional Laboratory Chiefs, and the Quality Assurance Officer;

b) Chair a MOE Laboratories Quality Assurance Committee to ensure an appropriate and, where possible, consistent approach to data and operational quality management;

c) Chair a Laboratory Users Committee to include personnel from other Branches to determine analytical workloads and assist in defining the quality and type of service required;

d) Ensure regular meetings of the Managers, to identify and resolve problems identified through the quality management program;

e) Ensure that laboratory protocols and procedures are exposed to peer review, and that they meet accepted international standards.

2.1.2. Section Managers & Regional Laboratory Chiefs

a) Maintain regular contact with clients to discuss data quality needs;

b) Ensure that the quality of all analytical procedures under their control is managed and documented in accordance with this Plan;

c) Define the Section Quality Management Strategy and identify the individual(s) responsible for Section QA Coordination;

d) Establish a Section Technical Committee to assist the Section QA Coordinator in developing and implementing the Section QA Workplan;

e) Work with the Laboratory Services Branch QA Office in setting their Section QA goals and objectives, in identifying and resolving problems, and in scheduling laboratory QA audits;

f) Ensure that staff participate in the various system and performance audits that may be scheduled;

g) Participate in the Laboratories QA Committee meetings, to advise on the progress of their QA Program, and to approve and ensure the timely adoption of QM/QA/QC protocols relevant to their Section;

h) Provide such assistance as may be required to ensure all goals of the Plan are achieved.

2.2. QUALITY MANAGEMENT OFFICE

2.2.1. Supervisor

a) Review and report on the adequacy of all QM/QA/QC activities undertaken by Laboratory Managers, Regional Laboratory Chiefs, and their staff in accordance with their responsibilities as outlined in section 2;

b) In response to the requirements of the Director, Managers and Regional Laboratory Chiefs, monitor the activities of the Section Technical Committees to promote, where appropriate, a consistent approach in the development of QM/QA/QC policies and directions;

c) Provide information to, and develop training programs for, all laboratory staff on QA/QC as it applies to routine analytical activities;

d) Develop and circulate guidelines for consideration by project, field, and laboratory staff in the development of QA manuals, procedures and programs, and finalize adopted guidelines as ministry policies and protocols;

e) Advise Laboratory and Program Managers of any QA needs which will enhance the quality of Ministry programs, particularly where they impact on the quality of samples submitted to the laboratories.

2.2.2. Staff:

a) Assist senior staff in determining and meeting the data quality requirements of all Ministry programs;

b) Oversee the development and implementation of a documented Quality Management System, and to evaluate each Section and Regional QA Program;

c) Advise Regional and Sectional Technical Committees in all aspects of operational and data quality maintenance, assessment, and documentation;

d) Establish regular QA Program Audits to ensure that QA/QC procedures are being implemented, data quality is being documented, and problems are being resolved;

e) Establish regular Performance Audits of analytical systems through submission of blind check samples/standards, and by monitoring and evaluating performance in interlaboratory comparison studies;

f) Assist Program Managers in auditing the performance of field operations by means of field blanks, control standards, and other appropriate measures;

g) Prepare and circulate protocols as necessary to establish a consistent approach for reporting and interpreting analytical data;

h) Ensure that appropriate checks are performed on those laboratories contracted to provide analytical services;

i) Prepare and validate control and performance audit standards and samples for use by field and laboratory personnel in documenting the quality of their work, and by the QA Office in auditing performance.

2.3. LABORATORIES STAFF

2.3.1. Supervisors shall:

a) Ensure that all analytical systems are operated in a state of statistical control;

b) Ensure that all analytical procedures are fully documented and that QA/QC requirements are defined and implemented;

c) Ensure that all method approval protocols are followed;

d) Ensure that staff are advised of the process for stopping and re-initiating analyses when problems have been flagged by the QA/QC process.

2.3.2. Senior Scientists and Senior Technicians shall:

a) Verify that QA/QC tasks are carried out as required;

b) Provide documentation of methods, procedures and protocols, and prepare quality assessment reports based on regular review of analytical QC records and observations;

c) Ensure that new methods are properly tested for ruggedness and reliability and are suitable for the samples to be analyzed;

d) Ensure that method precision, accuracy, biases, recovery and specificity are properly documented and reported to the Section Technical Committee;

e) Ensure that no analytical process is implemented without manager approval;

f) Follow Good Laboratory Practices at all times when specific QA/QC protocols have not been defined;

g) Ensure that staff perform all required QA/QC tasks in accordance with established Section QA/QC protocol;

h) Ensure that all instances of system or component control failure are documented and problems resolved before reinstating or continuing the process.

2.3.3. Other Analysts and Staff shall:

a) Carry out their regular duties in accordance with the QA/QC protocols established within their Section;

b) Carry out the QA/QC tasks assigned, record the results of all QC checks in the required format, and maintain such records so they are available and data quality can be traced and verified;

c) Assist in identifying and resolving operational or data quality problems;

d) Document all instances of failure to meet the required control limits, report them to the appropriate unit leader or supervisor and obtain supervisory approval to proceed.

2.4. QA COMMITTEES AND GROUPS

2.4.1. MOE Laboratories QA Committee

Quarterly meetings are held between the Section Managers and the Regional Laboratory Chiefs, chaired by the Director, Laboratory Services Branch. The QA Office and Section QA Coordinators present highlight reports on the status of their QM Workplan. Recommendations for QM/QA/QC and related protocols or procedures shall be presented for discussion, approval, and adoption by this committee.

2.4.2. QA Coordination Committee

Regular meetings are held between the QA Officer and the Section QA Coordinators to promote a consistent Ministry-wide approach to analytical data quality, documentation and data interpretation; to document these practices for management approval, and to respond to requests for information or protocol review, and development from the Laboratory Managers.

2.4.3. Section Technical Committees (STC)

Each Section Manager maintains a Section Technical Committee to coordinate and manage Section technical and QA/QC activities. The STC includes the Supervisors, the Branch Quality Assurance Officer plus other designated staff.

The STC, chaired by the Section QA Coordinator, is responsible for the development, documentation, and implementation of the Section Quality Assurance Program. It meets regularly to review existing QA/QC and analytical procedures, identify problems, recommend essential QA/QC activities, define protocols, and report on progress. Agendas are prepared, as well as

minutes, and other progress reports as required. The Manager, Director, and Quality Assurance Office are copied on all such documents.

In particular each Section Technical Committee will:

a) Document the Section Quality Assurance Program and ensure its implementation on a unit-by-unit basis;

b) Prepare and schedule a Section QA Workplan which identifies the specific tasks assigned to staff and deadlines for completion,

c) Ensure that all analytical and quality control procedures required are documented in the appropriate Section Method, QA, or QC manuals;

d) Ensure that the performance characteristics of all analytical systems are documented, and that appropriate control limits are established to maintain optimum performance;

e) Document all changes in Method or Quality Control protocols and procedures;

f) Participate in the development, documentation, and implementation of protocols related to the measurement, reporting, interpretation, or management of analytical data;

g) Participate in Sectional system, analytical and performance audits.

MOE LABORATORIES QUALITY MANAGEMENT PLAN - 1991

3. GLOSSARY OF QM TERMS

3.1. INTRODUCTION

QUALITY IS CONTROLLED by the implementation of QC activities which monitor, maintain, and re-establish the quality or performance of a process or system component to meet predetermined criteria.

QUALITY IS ASSURED by the implementation of QA activities which will ensure that the most significant or most likely causes of degradation in system quality are identified and controlled to minimize their impact, and by the implementation of appropriate performance monitoring, control, and remedial action activities.

QUALITY IS VERIFIED by the implementation of AUDITS. These activities are undertaken at the request of management by independent personnel (not involved in the specific operation under review), in accordance with written procedures or checklists, to evaluate on the basis of objective evidence, the completeness and effectiveness of an operation. Self evaluation by technical or supervisory staff required as part of the QA program does not constitute an audit.

AUDITS will address four areas, namely, the QA program itself, the way in which it is implemented, the procedures and protocols employed, and the quality level achieved.

3.2. QUALITY TERMS

3.2.1. Quality

The ability of a system and its product to meet its intended purpose.

Product quality is a direct reflection of the extent to which system quality is controlled. Quality must be built into the system by means of a rigorous planning process. It must then be monitored and documented. Evidence of system and product quality must be available for assessment and audit.

3.2.2. Data Quality

The quality of an analytical measurement includes both qualitative and quantitative components. The qualitative component includes:

- proper sub-sampling of a well homogenized sample;
- proper preservation, storage and handling;
- proper selection and implementation of methodology;
- adequate separation and identification of the analyte.

The quantitative component includes:
- use of accurate standards for calibration;
- controlled calibration and regular standardization;
- efficient recovery of the analyte;
- adequate correction for method blanks, recovery, and interference from other sample constituents.

Measurement estimates will only be close to the true value if the measurement process is controlled to minimize the possibility of significant sources of bias.

Both aspects of data quality should be evaluated by the introduction of appropriate PERFORMANCE MONITORING systems and the setting of criteria based on predetermined DATA QUALITY OBJECTIVES.

3.2.3. Project Quality

In addition to the laboratory impact on data quality, the overall design and implementation of the field program can impact severely on data quality.

Project Quality is demonstrated by evidence that:
- data quality needs have been defined and met;
- the correct samples were taken from the environment;
- the samples taken represent the specific attributes to be studied:
- sample validity is not degraded;
- the impact of environmental variability on data interpretation has been accounted for;
- the impact of the field activity can be assessed;
- the impact of laboratory procedures, including sample storage and analysis, can be assessed;
- all sources of error have been minimized, and appropriate controls have been established to ensure this;
- data has been interpreted with due regard for the uncertainties introduced by all aspects of the investigation;
- the impact of environmental variability and field and lab activity does not preclude the attainment of project objectives.

3.2.4. Project Quality Planning

Activities undertaken during project development to ensure that the project's quality needs will be met by the operational services available (field, laboratory or other), and that all critical facets of the project will be accompanied by appropriate QA/QC activity.

Project quality planning requires multi-disciplinary co-operation to ensure all are aware of their roles. It is increasingly accepted practice that Project Plans must describe the various field and laboratory QA/QC protocols and procedures required, in addition to the project description. This may be done

by reference to appropriate documents including operational services Method and QM/QA/QC Manuals.

3.3. QUALITY MANAGEMENT TERMS

3.3.1. Quality Management (QM)

Activities undertaken by Management in operational areas to establish and maintain staff accountability for the quality of operation.

They will include assignment of responsibilities, definition of tasks, protocols and procedures, and audit mechanisms, to determine and maintain the desired level of product quality, to document the mechanisms for achieving it, and to verify it is being achieved.

3.3.2. Quality Assurance (QA)

Activities undertaken by Supervisory personnel in operational areas to define the way in which specific tasks are to be performed to ensure that the final product will meet a desired level of quality.

QA includes documentation of procedures, identification of critical points within the process which require monitoring by Quality Control procedures, the level of quality achieved, problems encountered, and corrective actions undertaken.

3.3.3. Quality Control (QC)

Activities undertaken at the Technical level prior to use of critical system components, to determine and verify their suitability, to eliminate defective components, and to forestall release of inappropriate or erroneous product.

QC will address the quality of supplies, reagents, containers, instrument calibration, equipment maintenance, method development and evaluation, staff training, etc.

3.3.4. Performance Monitoring (PM)

Activities undertaken at the Technical level, while the system is in service, to determine, verify, and document the proper and satisfactory operation of a process, and to demonstrate and document the actual level of quality achieved.

Typical activities include field/lab blanks, duplicate samples, duplicate analyses, spike recovery, analysis of control/reference materials, etc.

3.4. AUDIT TERMS

3.4.1. Program Audit

Evaluation of the quality management plan in terms of completeness and state of implementation.

A program audit includes a review and evaluation of the documentation and implementation of Quality Management strategies and the documentation of the Quality Assurance program.

3.4.2. System Audit

General evaluation of the facilities and operations to determine compliance with the requirements of the QM Plan and QA/QC and Operational protocols.

3.4.3. Procedure Audits

Detailed evaluation of routine activities relative to documented operational and analytical procedures to verify proper implementation.

3.4.4. Performance Audit

Evaluation of data documenting the degree of success achieved by the QA/QC activities relative to documented DQO's.

A performance audit includes review of existing routine control and performance monitoring data, and control charts, as well as independent assessment by submission of blind test samples.

3.5. CONTROL TERMS

3.5.1. Control

The establishment of a standard or criterion, and appropriate limits relative to that standard, to determine the acceptability of a system or product, and deliberate action to correct deficiency inferred to have occurred when that limit is exceeded.

The criteria for setting the standard and acceptable limits may be quite arbitrary. However, when the limits have been exceeded the system or product is defined to be defective.

3.5.2. Statistical Control

The establishment of a standard and limits for acceptability based on statistical techniques using data which can be shown to be more or less normally distributed, and therefore inferred to be descriptive of a system in control.

Reliable measurement systems will generate data which is essentially normally distributed. Therefore the probability of observing values widely divergent from the average can be predicted. When such values are observed, they are taken as evidence of system failure.

3.5.2.1. Simple Statistical Control (Within-run precision control)

The ability of a well defined and implemented system to maintain an optimal level of performance without external adjustment.

Performance criteria for this level of control are based on the demonstrated repeatability of the system, based on replication within a single run or batch.

3.5.2.2. Complex Statistical Control (Between-run bias control)

The ability of an operator to reset and initiate a system on a day-to-day basis so that;

- there is no significant degradation in repeatability,
- there is no significant bias (or inaccuracy),
- there is no significant variation in bias day-to-day.

Significant change in variability is determined in terms of the ratio of between-run to within-run estimates of standard deviation (or variance). As a general rule of thumb a ratio greater than 1.5 is significant if both estimates are based on a similar number of replicates (> 20).

3.5.3. Standard Deviation

An estimate of the anticipated spread of repeated measurements about their average value, obtained under specified conditions.

Various estimates include: within-run, between-run, total method or instrument performance, between-laboratory, etc. Estimates of S are used to set warning or control limits about an expected value, and for setting method detection limits.